510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K093739

MAY - 7 2010

1. Submitter's Identifications:

Ningbo Diaier Electronic Co., Ltd.
No.1, Beixing Rd.,Yaoxi Industrial Zone, Yuyao City, Zhejiang, China
Contact: Lao XiKun
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Date of Summary Preparation: May 25, 2009

2. Name of the Device:
Blood Pressure Monitor; W & A series including the following models:
   - WA100/WA200/WA300/WB100/WB200/WD100/WE100/WF100 for wrist type, and
   - AA100/AA200/AB100/AC100/AD100 for upper arm type.

3. Classification information:

Regulation Number	: 870.1130
Medical Specialty	: Cardiovascular Devices
Product Code	: DXN
Device Class	: II
Tier	: II

4. Device Description:

Basically the measuring system were composite of blood pressure measuring circuit via Oscillometric method, pressure sensor, measuring cuff at arm, pneumatic pump, inflation and deflation system, housing, display LCD, and measuring software...and so on.

The main operation for the blood pressure measurement is carried out in such a way that the measuring cuff at arm is inflated to the estimated pressure level, then deflated to zero automatically. During the inflation and deflation, the pressure change with respective of time were recorded as the data base of measurement. Then the following measuring results will be calculated against the measurement data base :
- Blood pressure information including systolic and diastolic pressure (calculated via Oscillometric method)
- Heart beat rate.

For this submission, two different type of blood pressure monitors are to be included in this 510(K) submission, the W series wrist type/model WA100/WA200/WA300/WB100/ WB200/WD100/WE100/WF100 and A series upper arm type/model AA100/AA200/ AB100/AC100/AD100. The main intended use for these two type of blood pressure monitor is as the description of the following section:

In addition to the main blood pressure and heart beat rate measuring function, the W series wrist type/model WA100/WA200/WA300/WB100/WB200/ WD100/WE100/WF100 and A series upper arm type/model AA100/AA200/AB100/AC100/AD100 blood pressure monitors provide also the memory function for user to store the result of measurement.

5. Intended Use:

"WA100/WA200/WA300/WB100/WB200/WD100/WE100/WF100 blood pressure monitor measures automatically human being systolic, diastolic blood pressure and heart beat rate from wrist by using the Oscillometric method for the individual of the age over 18 years old. The measurement values can be read out on the LCD panel and kept in the memory for home care use(without the involvement of professional physician)"

"AA100/AA200/AB100/AC100/AD100 blood pressure monitor measures automatically human being systolic, diastolic blood pressure and heart beat rate from upper arm by using the Oscillometric method for the individual of the age over 18 years old. The measurement values can be read out on the LCD panel, kept in the memory for home care use(without the involvement of professional physician)"

6. Comparison to the 510(k) Cleared Device (Predicate Device):
   1> Diaier model WA400 (K091553) for W series wrist model models: WA100/WA200/ WA300/WB100/WB200/WD100/WE100/WF100 .
   2> Diaier model AA300(K91553) for A series upper arm model : AA100/AA200/AB100 /AC100/AD100.

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
   Compliance to applicable voluntary standards includes ANSI/AAMI, SP 10-2002, as well as EN 60601-1, and EN 60601-1-2 requirement.

   In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

8. Conclusions

   The Diaier W series model WA100/WA200/WA300/WB100/WB200/WD100/WE100/WF100 blood pressure monitor (measurement at wrist) has the same intended use and technical characteristics as the Diaier 510K cleared model WA400(K091553) , and A series model AA100/AA200/AB100/AC100/AD100 blood pressure monitor (measured at upper arm) has the same intended use and technical characteristics as the Diaier 510K cleared model AA300(K091553).

   Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared devices.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device, and the new models as mentioned on this submission are considered substantial equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ningbo Diaier Electronic, Co., Ltd.
c/o Mr. Lao XiKun
Official Correspondent
No 1., Beixing Rd., Yaoxi Industrial Zone
Yuyao City, Zhejiang
CHINA

MAY - 7 2010

Re: K093739
Device Name: Blood Pressure Monitor, Models WA100, WA200, WA300, WB100, WB200, WD100, WE100, WF100, AA100, AA200, AB100, AC100, and AD100
Regulation Number: 21 CFR 870.1130
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: April 16, 2010
Received: April 21, 2010

Dear Mr. XiKun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

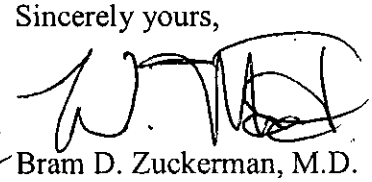
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K093739

Device Name: Blood Pressure Monitor, W series wrist type models : WA100/WA200/ WA300/WB100/WB200/ WD100/WE100/WF100 and A series upper arm type models: AA100/AA200/AB100/AC100/AD100

Indications For Use:

"WA100/WA200/WA300/WB100/WB200/WD100/WE100/WF100 blood pressure monitor measures automatically human being systolic, diastolic blood pressure and heart beat rate from wrist by using the Oscillometric method for the individual of the age over 18 years old. The measurement values can be read out on the LCD panel and kept in the memory for home care use(without the involvement of professional physician)"

"AA100/AA200/AB100/AC100/AD100 blood pressure monitor measures automatically human being systolic, diastolic blood pressure and heart beat rate from upper arm by using the Oscillometric method for the individual of the age over 18 years old. The measurement values can be read out on the LCD panel, kept in the memory for home care use(without the involvement of professional physician)"

Prescription Use ____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093739